510(k) Summary of Safety and Effectiveness for the

ADVIA® Chemistry Cystatin C Method

MAR 1 1 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: __k083906_____

B. Date of Preparation: December 22, 2008

C. Proprietary and Established Names:

ADVIA® Chemistry Cystatin C Reagent
ADVIA® Chemistry Cystatin C Calibrator

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Kira Gordon, Sr. Regulatory Affairs Specialist

Office: (914) 524-2996 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Chemistry Cystatin C Reagent

1. Regulation section: 21 CFR § 862.1225 Creatinine, test system.

2. Classification: Class II

3. Product Code: NDY, Test, Cystatin C

4. Panel: Clinical Chemistry

ADVIA Chemistry Cystatin C Calibrator

1. Regulation section: 21 CFR § 862.1150 Calibrator

2. Classification: Class II

3. Product Code: JIT, calibrator secondary

4. Panel: Clinical Chemistry

F. Predicate Device:

ADVIA Chemistry Cystatin C reagent is substantially equivalent to the Dade Behring N Latex Cystatin C reagent cleared under k041878

ADVIA Chemistry Cystatin C calibrator is substantially equivalent to the Dade Behring N Protein Standard UY cleared under K003501.

G. Device Description:

The CYSC latex reagent is a suspension of uniform latex particles coated with anti-cystatin-C antibody. When serum or plasma containing cystatin C is mixed with the latex reagent, agglutination takes place resulting in an increase in turbidity. This turbidity is measured at 571 and 805 nm. The cystatin C concentration in serum or plasma is determined from a calibration curve that is generated with the calibrators.

H. Intended Use:

Reagent: For in vitro diagnostic use in the quantitative determination of Cystatin C (CYSC) in human serum or plasma on the ADVIA Chemistry systems. Measurement of Cystatin C aids in the diagnosis and treatment of renal disease.

Calibrator: For in vitro diagnostic use in the calibration of Cystatin C method on ADVIA Chemistry systems.

I. Substantial Equivalence Information:

The ADVIA Chemistry Cystatin C Method and (formerly) Dade Behring, Inc., N Latex Cystatin C methods were compared. A comparison of the important similarities and differences between the devices and the predicates is provided in the following tables:

Similarities		
Item	Device	Predicate
Analyte	Cystatin C	Cystatin C

Intended Use	Reagent: for in vitro diagnostic use in the quantitative determination of cystatin C in human serum and plasma on the ADVIA Chemistry systems.Measurement of cystatin C aids in the diagnosis and treatment of renal diseases. Calibrator: For in vitro diagnostic use in the calibration of the Cystatin C method on ADVIA Chemistry systems.	Reagent: N Latex CYSC method is an in vitro diagnostic kit for the quantitative determination of cystatin C in human serum and heparinized plasma. Cystatin C measurements are used in the diagnosis and treatment of renal diseases. Calibrator: For preparing reference curves for the immunonephelometric determinations of a-1-micorglobulin and Cystatin C using the BN systems.
Antibody	Rabbit Polyclonal antibodies to human Cystatin C	Rabbit Polyclonal antibodies to human Cystatin C
Format	Liquid	Liquid
Use of Calibrators	Yes	Yes
Traceability	internal standard of highly purified human cystatin C	internal standard of highly purified human cystatin C
Reference range	0.56– 0.95 mg/L	0.53 – 0.95 mg/L

Differences

Item	Device	Predicate
Sample Matrix	Serum , Heparinized Plasma, EDTA plasma	Serum or Heparinized Plasma
Reagents	Two: R1 (buffer), R2 (latex coated with anti-cystatin C antibody from rabbit) contained in system specific packaging	Three: (1) latex coated with anti-cystatin C antibody from rabbit, (2) Supplementary A (rabbit antibody), (3) Supplementary B (polyethylene glycol) in system specific packaging
Technology / Methodology	Latex enhanced turbidimetric assay	Particle enhanced immunonephelometric assay
Number of Calibrators	6 (5 provided in package and zero-calibrator – DI water)	1 (diluted on system to 6 levels)
Calibrators	Recombinant Cystatin C in human serum base (liquid)	Urinary proteins of human origin polygeline and preservatives (lyophilized)
Reportable range	0.1 – 8.0 mg/L	0.05 - 8.0 mg/L

J. Conclusion:

The ADVIA Chemistry Cystatin C Method is substantially equivalent to the A Dade Behring, Inc., N Latex Cystatin C method cleared under K041878. Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 11 2009

Siemens Healthcare Diagnostics
c/o Dr. Kira Gordon
511 Benedict Avenue
Tarrytown, New York 10591

Re: k083906
Trade/Device Name: ADVIA Chemistry Cystatin C Reagent
Regulation Number: 21CFR 862.1225
Regulation Name: Creatinine, test system
Regulatory Class: Class II
Product Code: NDY, JIT
Dated: December 23, 2008
Received: December 30, 2008

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k083906

Device Name:

ADVIA® Chemistry Cystatin C Reagent

ADVIA® Chemistry Cystatin C Calibrator

Indication For Use:

Reagent: For in vitro diagnostic use in the quantitative determination of Cystatin-C (CYSC) in human serum or plasma (lithium heparin, potassium EDTA) on the ADVIA Chemistry systems. Measurement of Cystatin C aids in the diagnosis and treatment of renal disease.

Calibrator: For in vitro diagnostic use in the calibration of Cystatin C method on ADVIA Chemistry systems.

Prescription Use ✓ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Ruth Chelen

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k083906